



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

CROOKS et al.

Title:

ANALGESIC USES OF NORKETAMINE

AND KETAMINE/NORKETAMINE

PRODRUGS.

Appl. No.:

10/714,643

Filing Date:

November 18, 2003

Examiner:

Yong Soo Chong

Art Unit:

1617

Confirmation

2532

Number:

Declaration Under 37 C.F.R. § 1.132

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

- 1. I, Mark S. Kleven, Ph.D., do hereby declare as follows.
- 2. My educational background, research experience, work experience, and professional memberships are described below.
- 3. My educational background is as follows:

Ph.D., Pharmacology, University of Minnesota School of Medicine, Minneapolis, MN, 1986. NIH Pre-Doctoral Fellow.

M.A., Physiological Psychology, Marquette University, Milwaukee, WI, 1979. B.A./B.S., Psychology, Biology/Applied Mathematics, Bemidji State University, Bemidji, MN, 1977. Honors Scholar (1974-1977); B.A., summa cum laude.

4. I have the following research experience and have published more than 70 peer reviewed articles, most in high impact journals.

In vivo/ex vivo neurochemistry, radioimmunoassay, immunohistochemistry, and receptor binding. Stereotaxic surgery (rats); in vivo brain microdialysis (rats); chronic indwelling cardiac catheters (rats and monkeys); ex vivo brain dissection (mice, rats and monkeys). In vivo, site-specific knock-down of gene expression using antisense and siRNA.

Operant behavior: conflict-procedure (pigeon); drug discrimination (mice, monkeys, pigeons, and rats); drug self-administration (monkeys, rats); conditioned avoidance responding (rats).

Unconditioned behavior: hypophagia (rats); stimulant-induced behaviors (mice, monkeys and rats); catalepsy (mice, monkeys and rats); 5-HT1A agonist-induced behaviors (rat); DOI-induced head twitches (rat); prepulse inhibition (rat); locomotor activity (mice, monkeys and rats), forced-swimming test (rat); tail suspension test (mouse); apomorphine-induced climbing (mouse); social-isolation (rat); dopamine-induced eye blinks (monkeys).

5. My work experience is a follows:

Yaupon Therapeutics, Inc. (2006-)

Vice President Preclinical Development

Direct GLP and non-GLP Efficacy, Safety, and Toxicology studies conducted primarily by CROs, but also by Yaupon staff, supporting IND submissions. Manage out-sourcing of IND-enabling Safety/Toxicology studies and have a key role for compiling new STTRs, IND and EMEA submissions. Am currently PI on an SBIR grant supporting a Phase I clinical trial for Attention Deficit Hyperactivity Disorder. Ongoing projects involve treatment of smoking cessation, methamphetamine abuse, ADHD, neuropathic pain, psoriasis, and cutaneous T-cell lymphoma.

Consultant (2005)

Behavioral Pharmacology / Preclinical development

University of Pennsylvania, Dept. of Psychology, Philadelphia, PA (2005-)

Visiting Scholar

Ongoing support and development of data gathering tools and analysis of in vivo electrophysiology and behavioral experiments. For example, assist in data analysis associating behavioral events with neuronal activity.

Scientific Commercialization LLC., (2004)

Principal, Head Early Phase R & D

Consulted and authored reports on treatment of coronary heart disease, e.g., aspirin resistance, antiplatelet activity of ADP inhibitors and PPAR- γ agonists. Assisted advice for a critical sNDA review and developed leads for a new line of business.

Pierre Fabre Médicament, CASTRES, France (1992-2004)

Institute de Recherche Pierre Fabre

Pierre Fabre Médicament, the pharmaceutical branch of Groupe Pierre Fabre, is France's second-largest private drug firm, allocating 140 million euros (ca. 23% of revenues) to research and development.

Head, Behavioral Pharmacology, Neurobiology II (1992-2004) Chargé de Mission, Fonction Support (2002-2004)

Directed pivotal in vivo studies leading to clinical development of more than six new chemical entities, (e.g., F15063 and others, e.g. eptapirone that are in Phase I-II clinical trials). Developed and implemented novel in vivo behavioral screening assays for schizophrenia, depression, and anxiety. Implemented in vivo gene-silencing constructs and intra-cranial delivery methods (e.g., siRNA and antisense).

The University of Chicago, Dept. of Pharmacological and Physiological Sciences,

Pritzker School of Medicine, Chicago, IL (1986-1992)

Assistant Professor (Research Associate (1989-1992)

Research Associate (1987-1989)

NIMH Post-Doctoral Fellow, Psychiatry (1986-1987)

Co-Principal Investigator on studies of pharmacological effects of acute and chronic cocaine in primates. Assisted direction of studies demonstrating the ability of dopamine D1 antagonists to block cocaine self-administration and its subjective effects in primates. Developed efficient behavioral methods in primates to test compounds for treatment of cocaine abuse. Principal Investigator on studies of cocaine neurotoxicity in rats. Characterized neurotoxic properties and structure-related activity of amphetamine-related compounds, such as the anorectic fenfluramine.

6. I am a member of the following professional organizations:

American Chemical Society, American Society for Pharmacology and Experimental Therapeutics; Collegium Internationale NeuroPsychopharmacologicum (Fellow);

College on Problems of Drug Dependence (Industrial Relations Committee: 1997-2000);

Drug Information Association;

European College of Neuropsychopharmacology;

European Behavioral Pharmacology Society (Executive Committee: 2001-2005);

Society for Neuroscience

7. I am providing this Declaration with respect to the reference B. Ebert *et al.*, European Journal of Pharmacology, Aug. 20, 1997, 333 (1):99-104, ("Ebert *et al.*") which was cited in the Office Action dated July 9, 2007, for the above-captioned application.

- 8. In Ebert et al., the last sentence states as follows: "Clinical studies are now under way to investigate whether orally administered (S)-norketamine may have fewer side effects than (S)-ketamine."
- 9. Ebert et al. has four authors: Bjarke Ebert, Soren Mikkelson, Christian Thorkildsen and Finn Molke Borgbjerb.
- 10. I have searched the online PubMed database by the following author names: Ebert B., Mikkelsen S., Thorkildsen C., and Borgbjerb, FM. The results of these searches are attached hereto respectively as EXHIBITS 1-4. I have also searched the Ovid database.
- 11. Neither the search of PubMed nor the Ovid database indicated that any of the authors of Ebert $et\ al$. has made a subsequent publication related to clinical studies of (S)-norketamine or norketamine.
- 12. I am not aware of any publications related to clinical trials of (S)-norketamine or norketamine, or any requests for regulatory approval of the therapeutic use of (S)-norketamine or norketamine. Given my level of professional knowledge related to (S)-norketamine or norketamine, I would have known if there had been any publications related to clinical trials requests for regulatory approval of the therapeutic use of (S)-norketamine or norketamine.

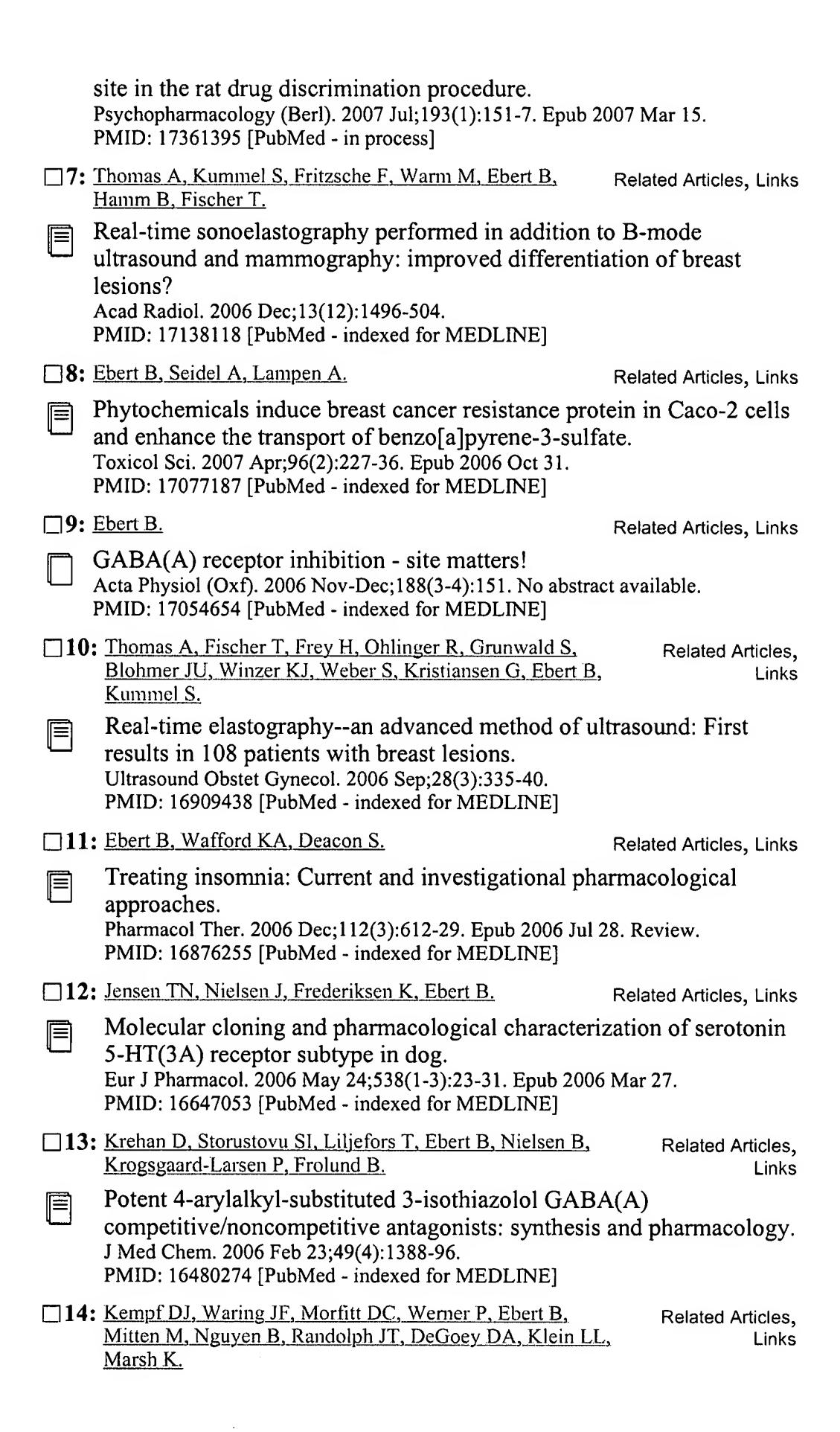
- 13. Because over ten years has passed since the publication of Ebert et al., and no public record of any clinical trials of (S)-norketamine or norketamine exists, I conclude that it is most certain that either (S)-norketamine was never tested in clinical trials, or if such clinical trials did occur, they were unsuccessful, discontinued and never publicized.
- 14. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title XVIII of the United States Code and that willful false statements may jeopardize the validity of this Application for Patent or any patent issuing thereon.

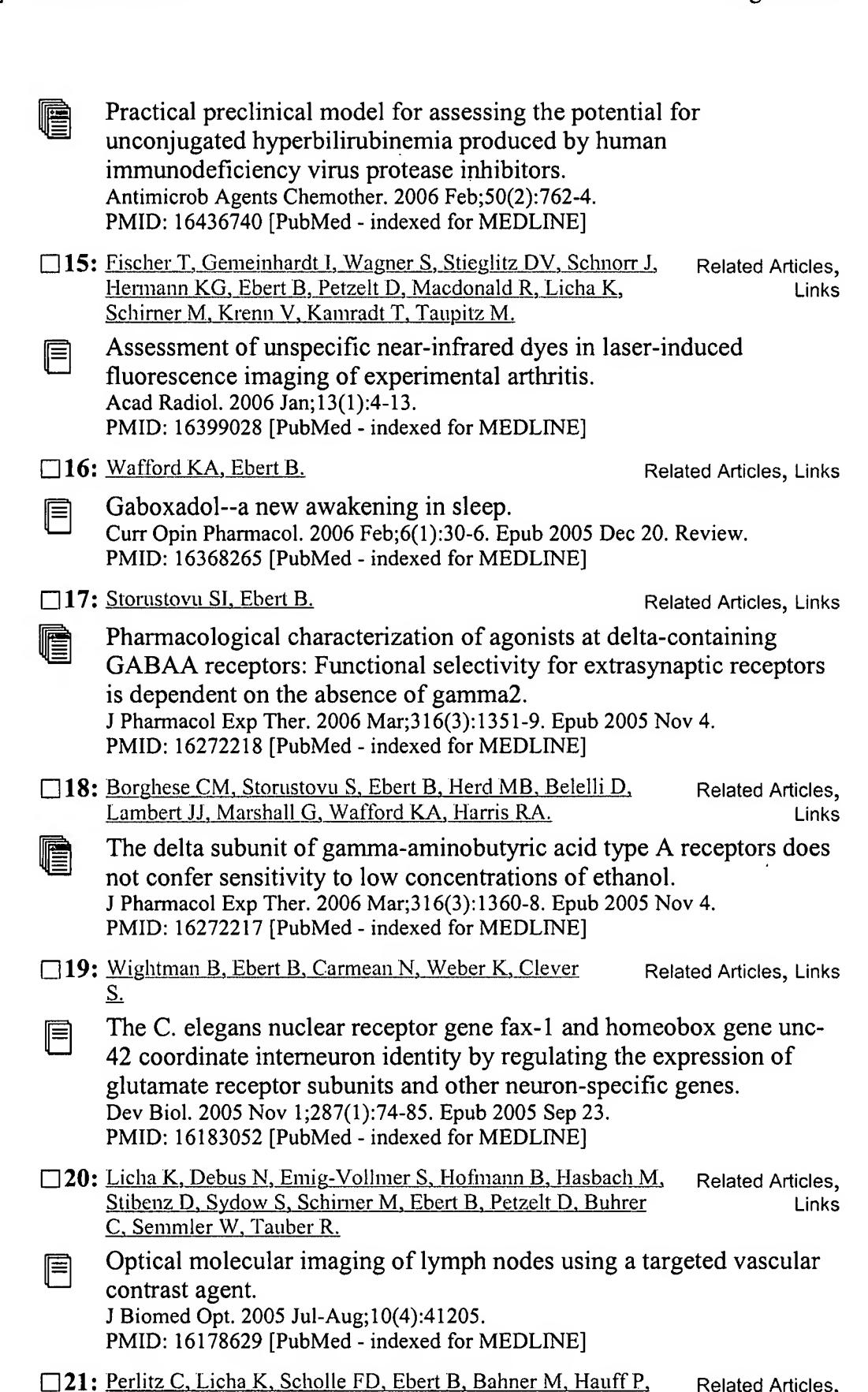
Dated: 049,2657

Mark S. Kleven, PhD

EXHIBIT 1

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Comparison of two tricarbocyanine-based dyes for fluorescence

Moesta KT, Schirner M.

Links

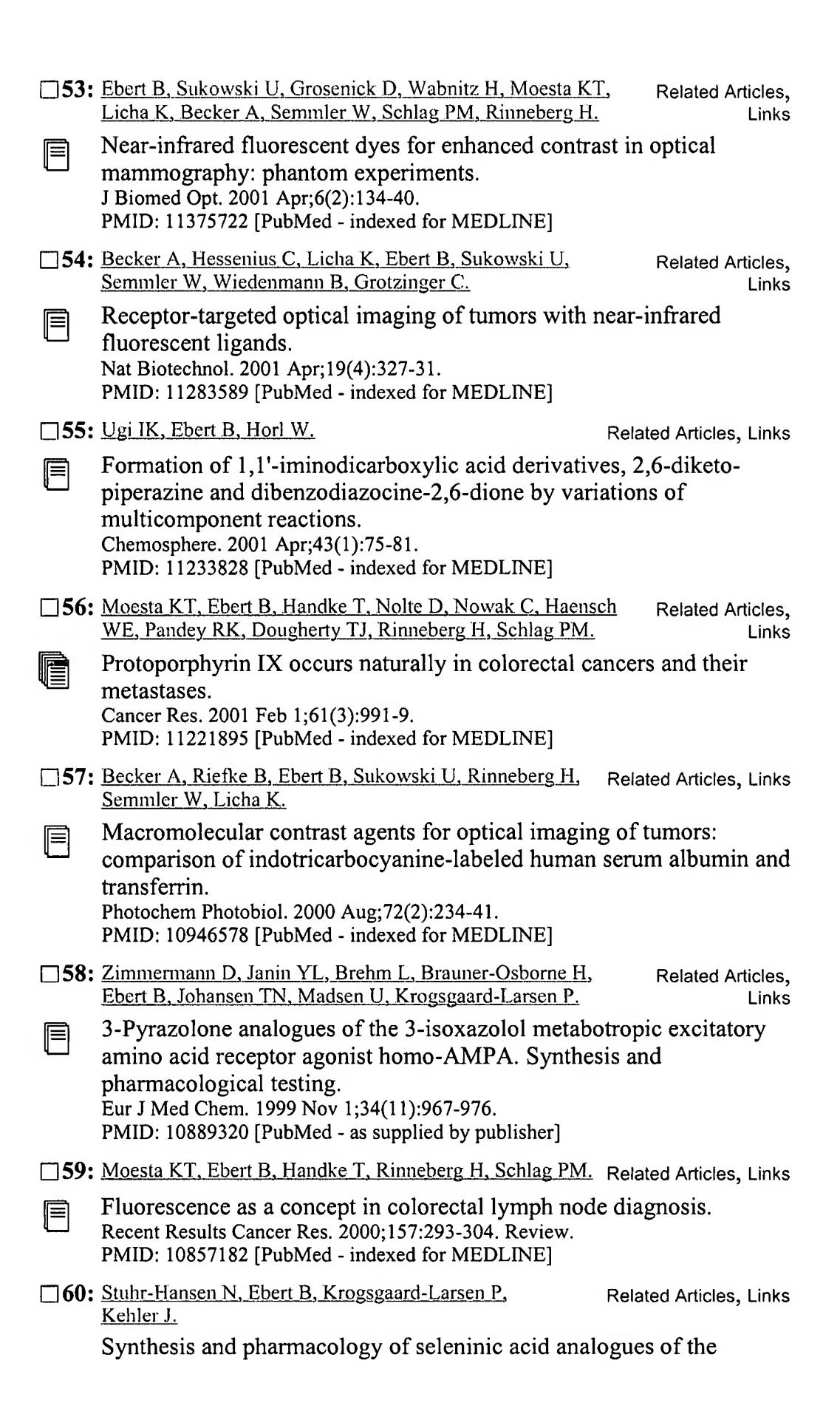
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	Aza-THIP and related analogues of THIP as GAB Bioorg Med Chem. 2003 Nov 17;11(23):4891-6. PMID: 14604650 [PubMed - indexed for MEDLINE]	A C antagonists.

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	Extrasynaptic GABA(A) channels activated by TH by diazepam in CA1 pyramidal neurons in the rat be slice. Mol Cell Neurosci. 2003 Sep;24(1):250-7. PMID: 14550784 [PubMed - indexed for MEDLINE]	
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	Time gated fluorescence spectroscopy in Barrett's Gut. 2003 Jan;52(1):28-33. PMID: 12477755 [PubMed - indexed for MEDLINE]	oesophagus.
□42:	Mortensen M, Frolund B, Jorgensen AT, Liljefors T, Krogsgaard-Larsen P, Ebert B.	Related Articles, Links
	Activity of novel 4-PIOL analogues at human alpha 2S GABA(A) receptorscorrelation with hydropho Eur J Pharmacol. 2002 Sep 13;451(2):125-32. Erratum in: 1 Oct 25;453(2-3):345-6. PMID: 12231381 [PubMed - indexed for MEDLINE]	obicity.
□43:	Bhargava S, Licha K, Knaute T, Ebert B, Becker A, Grotzinger C, Hessenius C, Wiedenmann B, Schneider-Mergener J, Volkmer-Engert R.	Related Articles, Links
	A complete substitutional analysis of VIP for bette properties. J Mol Recognit. 2002 May-Jun;15(3):145-53. PMID: 12203840 [PubMed - indexed for MEDLINE]	r tumor imaging
□44:	Licha K, Riefke B, Ebert B, Grotzinger C.	Related Articles, Links
	Cyanine dyes as contrast agents in biomedical opti Acad Radiol. 2002 Aug;9 Suppl 2:S320-2. No abstract avai PMID: 12188261 [PubMed - indexed for MEDLINE]	• •

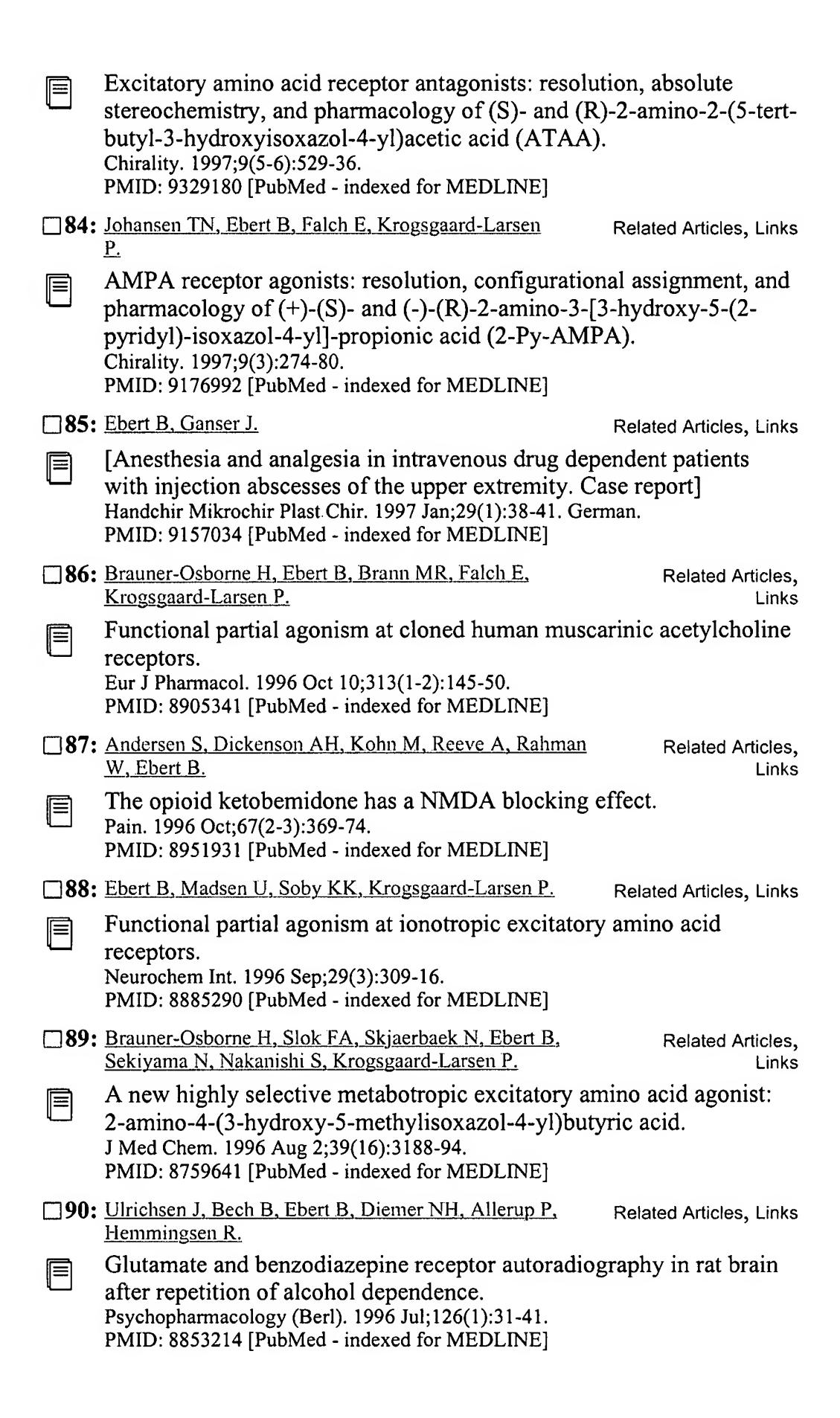
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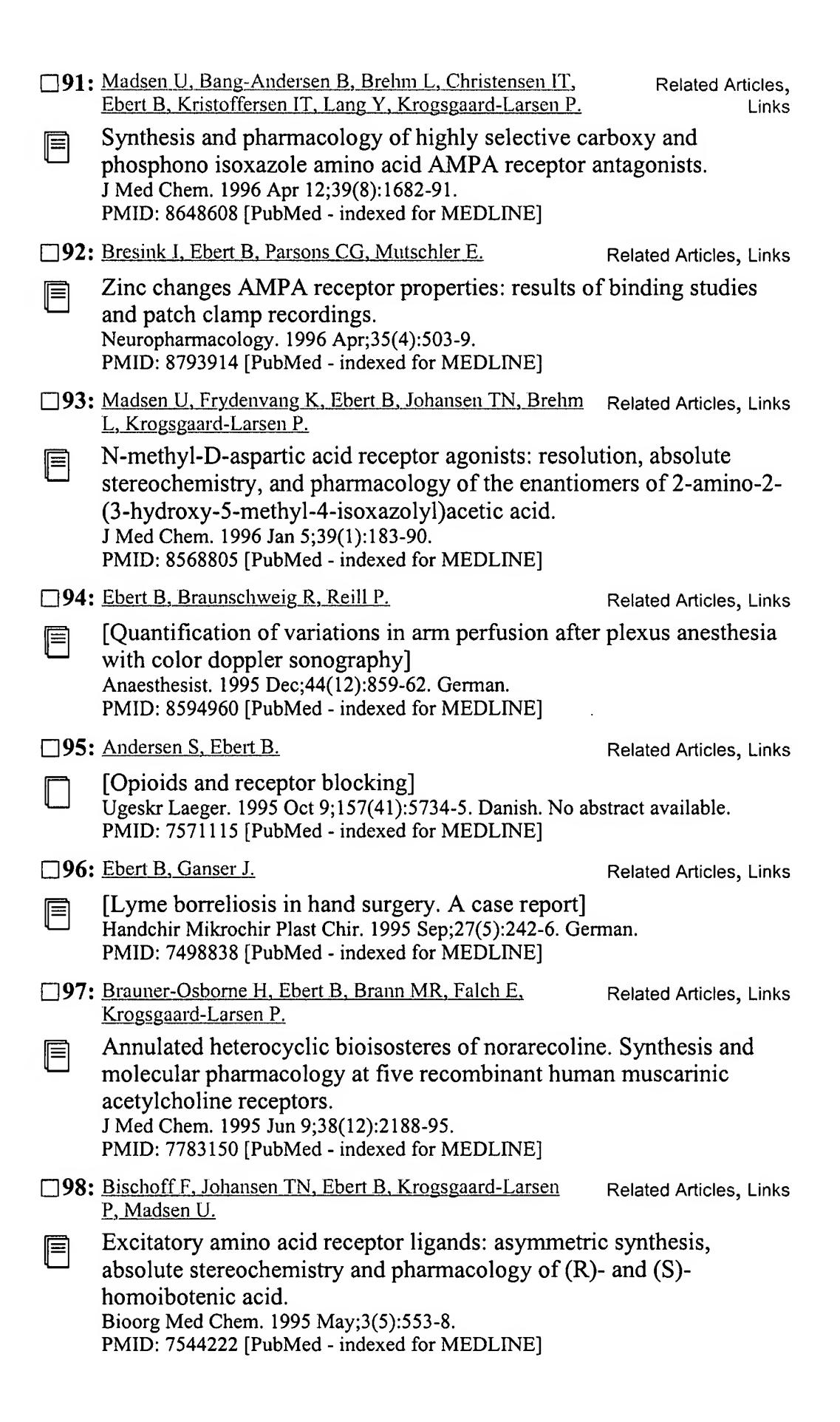


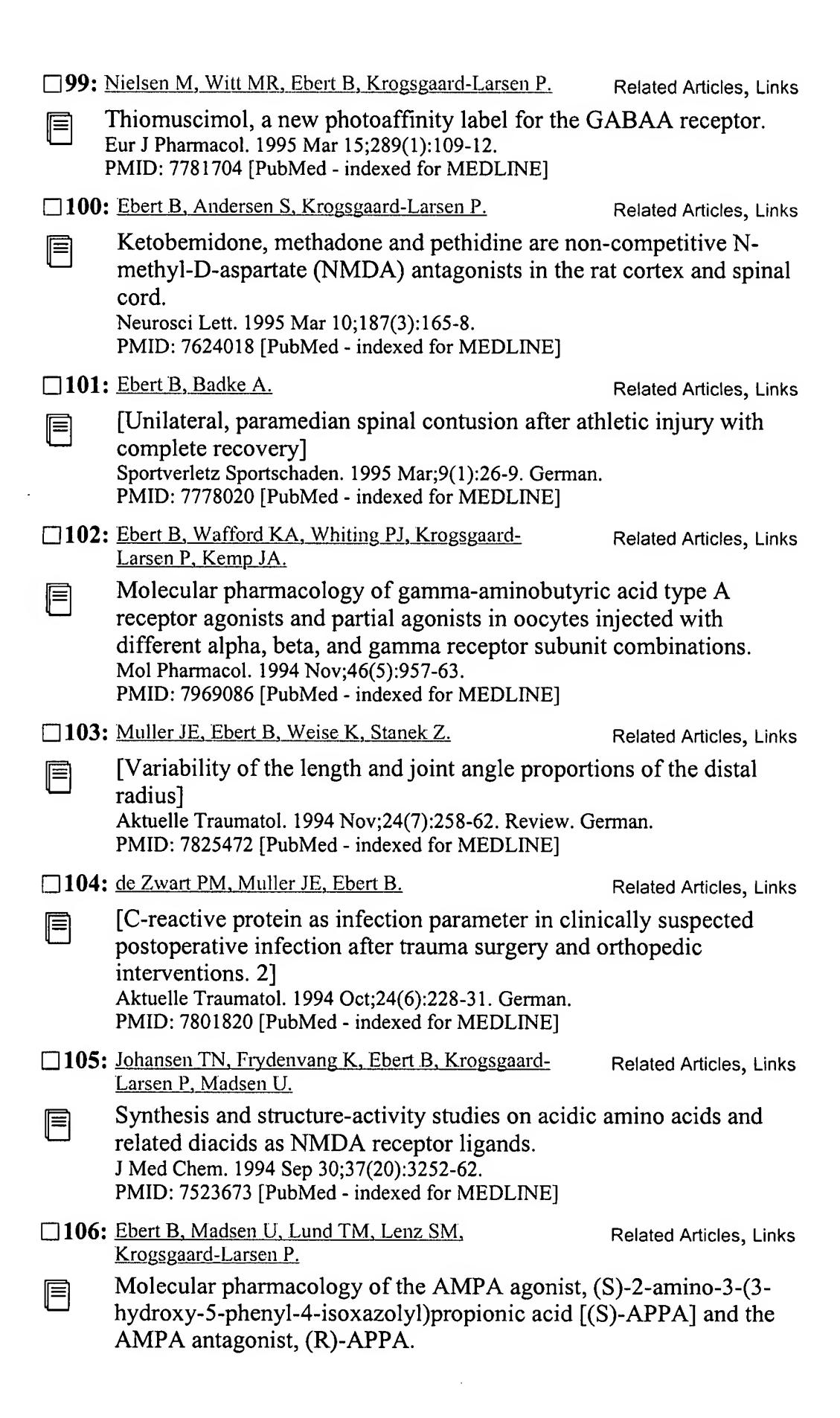
	inhibitory neurotransmitter gamma-aminobutyric at Org Lett. 2000 Jan;2(1):7-9. PMID: 10814232 [PubMed - indexed for MEDLINE]	icid.
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	Excitotoxic effects of non-NMDA receptor agonist corticostriatal slice cultures. Brain Res. 1999 Sep 11;841(1-2):143-59. PMID: 10546997 [PubMed - indexed for MEDLINE]	ts in organotypic
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	Characterization of a new AMPA receptor radiolig 3-(3-carboxy-5-methyl-4-isoxazolyl)propionic acid Eur J Pharmacol. 1999 Jun 4;373(2-3):251-62. PMID: 10414446 [PubMed - indexed for MEDLINE]	
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	Equilibrium binding characteristics of [3H]thiomus Neurochem Int. 1999 May;34(5):427-34. PMID: 10397371 [PubMed - indexed for MEDLINE]	scimol.
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	Synthesis and pharmacology of the baclofen homo (4-chlorophenyl)pentanoic acid and the R- and S-e amino-3-(4-chlorophenyl)pentanoic acid. J Med Chem. 1999 Jun 3;42(11):2053-9. PMID: 10354414 [PubMed - indexed for MEDLINE]	
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	Dextropropoxyphene acts as a noncompetitive N-me antagonist. J Pain Symptom Manage. 1998 May;15(5):269-74. PMID: 9654831 [PubMed - indexed for MEDLINE]	thyl-D-aspartate
□69 :	Falch E, Brehm L, Mikkelsen I, Johansen TN, Skjaerbaek N, Nielsen B, Stensbol TB, Ebert B, Krogsgaard-Larsen P.	Related Articles, Links
	Heteroaryl analogues of AMPA. 2. Synthesis, absolute stereochemistry, photochemistry, and structure-active J Med Chem. 1998 Jul 2;41(14):2513-23. PMID: 9651156 [PubMed - indexed for MEDLINE]	
□70 :	Ebert B, Thorkildsen C, Andersen S.	Related Articles, Links
	Ketobemidone plus (RS)-3-dimethylamino-1,1-dipheral (A29) is more potent at NMDA receptors than ketobe evidence for A29 as a non-competitive NMDA receptors than ketobe Pharmacol Toxicol. 1998 Mar;82(3):157-60. PMID: 9553996 [PubMed - indexed for MEDLINE]	emidone alone:
□71:	Johansen TN, Ebert B, Brauner-Osborne H, Didriksen M, Christensen IT, Soby KK, Madsen U, Krogsgaard-Larsen P, Brehm L.	Related Articles, Links
	Excitatory amino acid receptor ligands: resolution, a stereochemistry, and enantiopharmacology of 2-amin hydroxyisoxazol-5-yl)propionic acid. J Med Chem. 1998 Mar 12;41(6):930-9. PMID: 9526567 [PubMed - indexed for MEDLINE]	
□72:	Skjaerbaek N, Brehm L, Johansen TN, Hansen LM, Nielsen B, Ebert B, Soby KK, Stensbol TB, Falch E, Krogsgaard-Larsen P.	Related Articles, Links
	Aryl and cycloalkyl analogues of AMPA: synthetic, and stereochemical aspects. Bioorg Med Chem. 1998 Jan;6(1):119-31. PMID: 9502111 [PubMed - indexed for MEDLINE]	pharmacological
□73:	Ebert B.	Related Articles, Links
	[Medical insurance and forensic aspects of postmorterin cases of extra-clinical and accidental death] Versicherungsmedizin. 1997 Dec 1;49(6):216-9. German. PMID: 9490520 [PubMed - indexed for MEDLINE]	em examination
□74:	Ebert B, Ganser J.	Related Articles, Links
	[Axillary plexus catheter block in childhood and ado Handchir Mikrochir Plast Chir. 1997 Nov;29(6):303-6. Germ PMID: 9483427 [PubMed - indexed for MEDLINE]	-
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	Fetal villosity and microvasculature of the bovine plasecond half of gestation. J Anat. 1997 Nov;191 (Pt 4):517-27.	acentome in the

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□76:	Ebert B, Thompson SA, Saounatsou K, McKernan R,	Related Articles, Links
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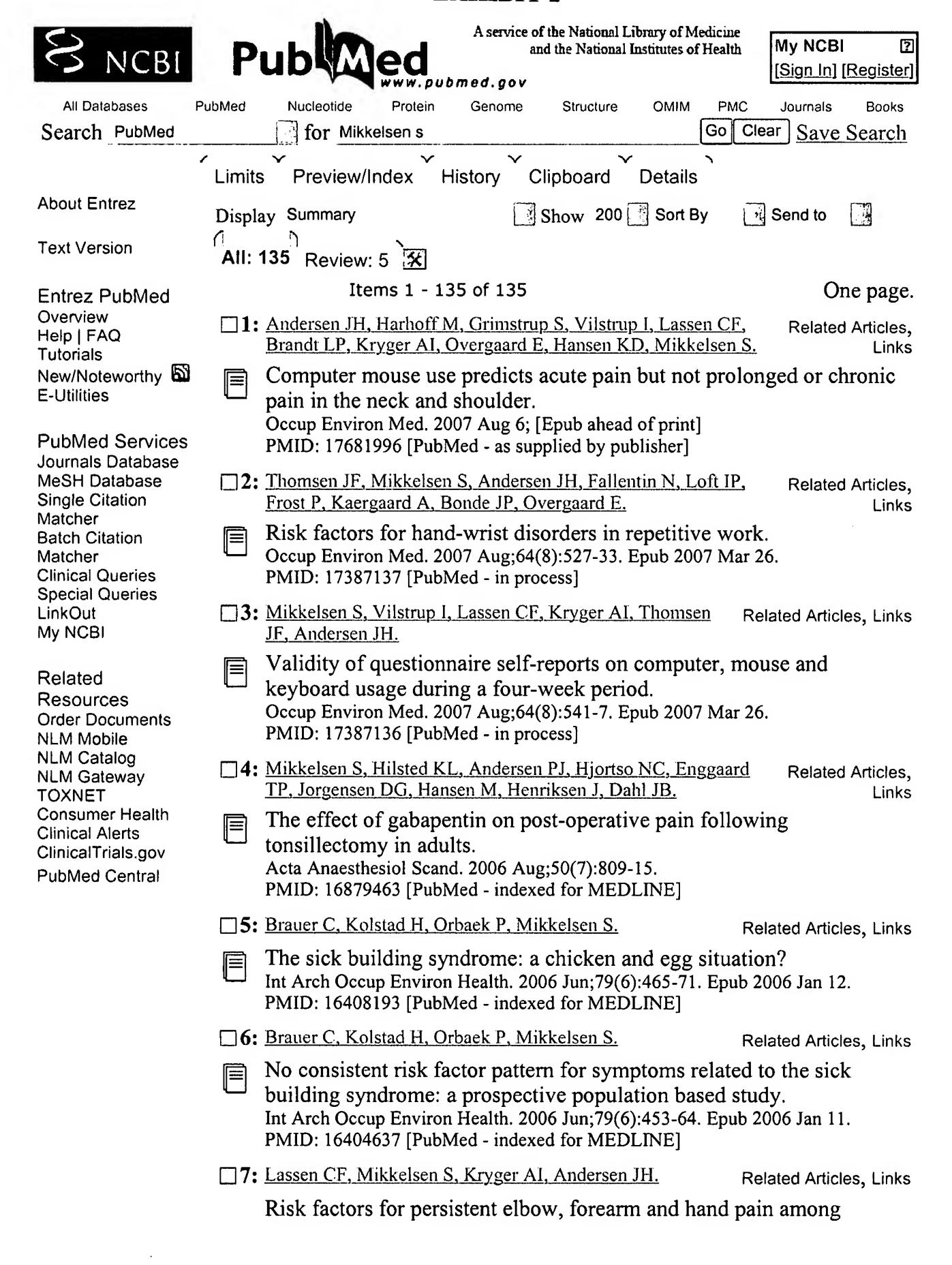
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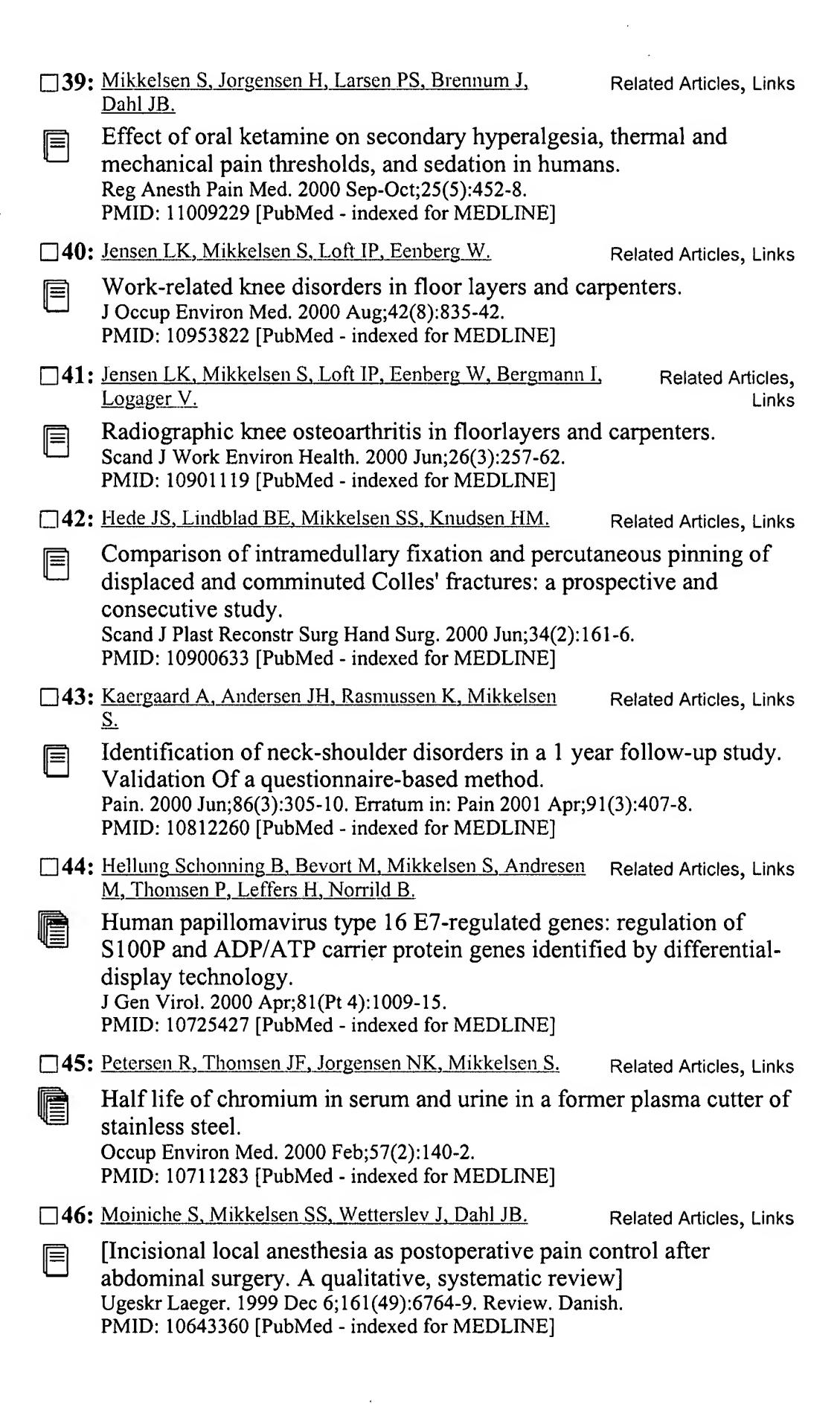


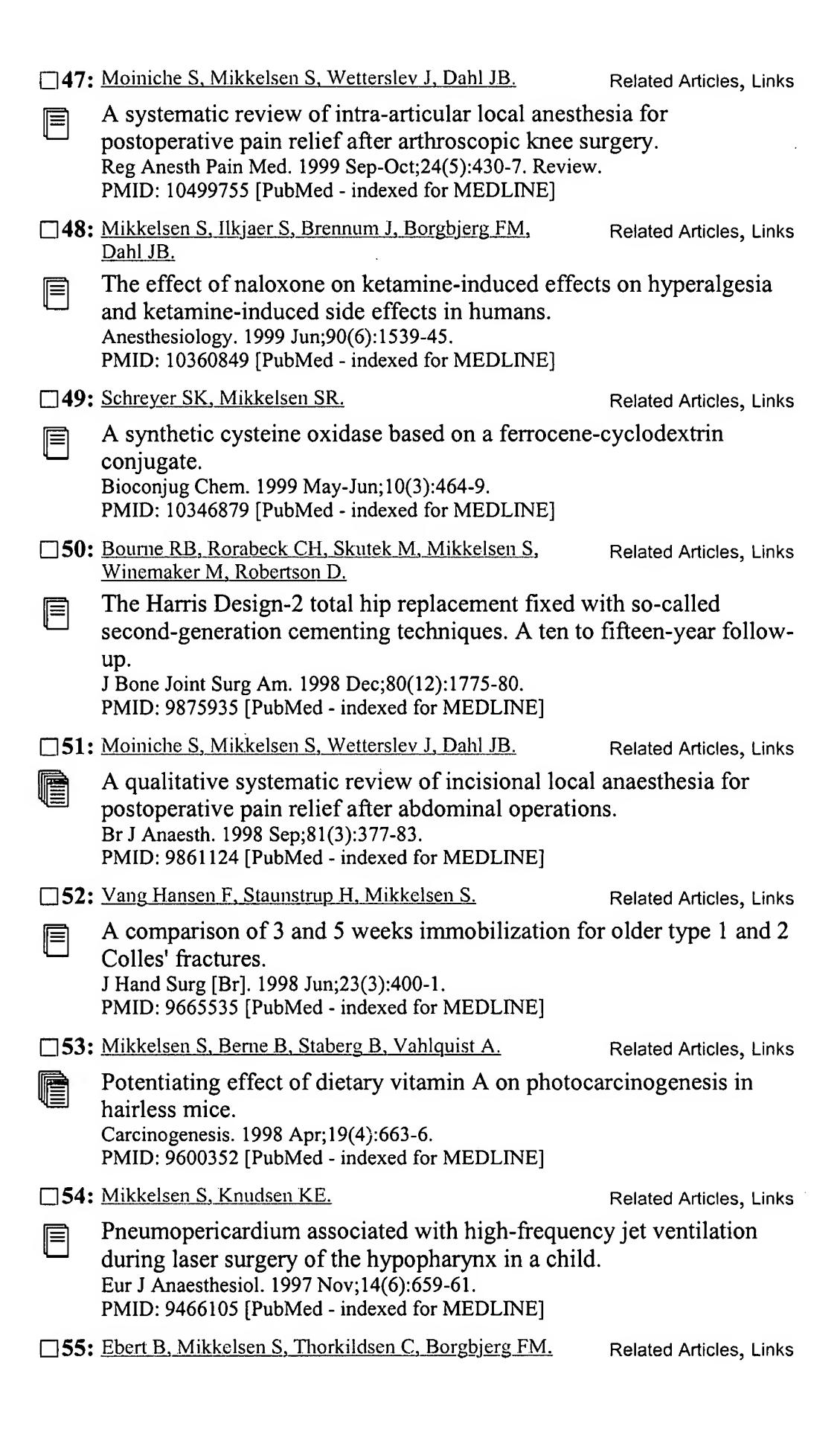
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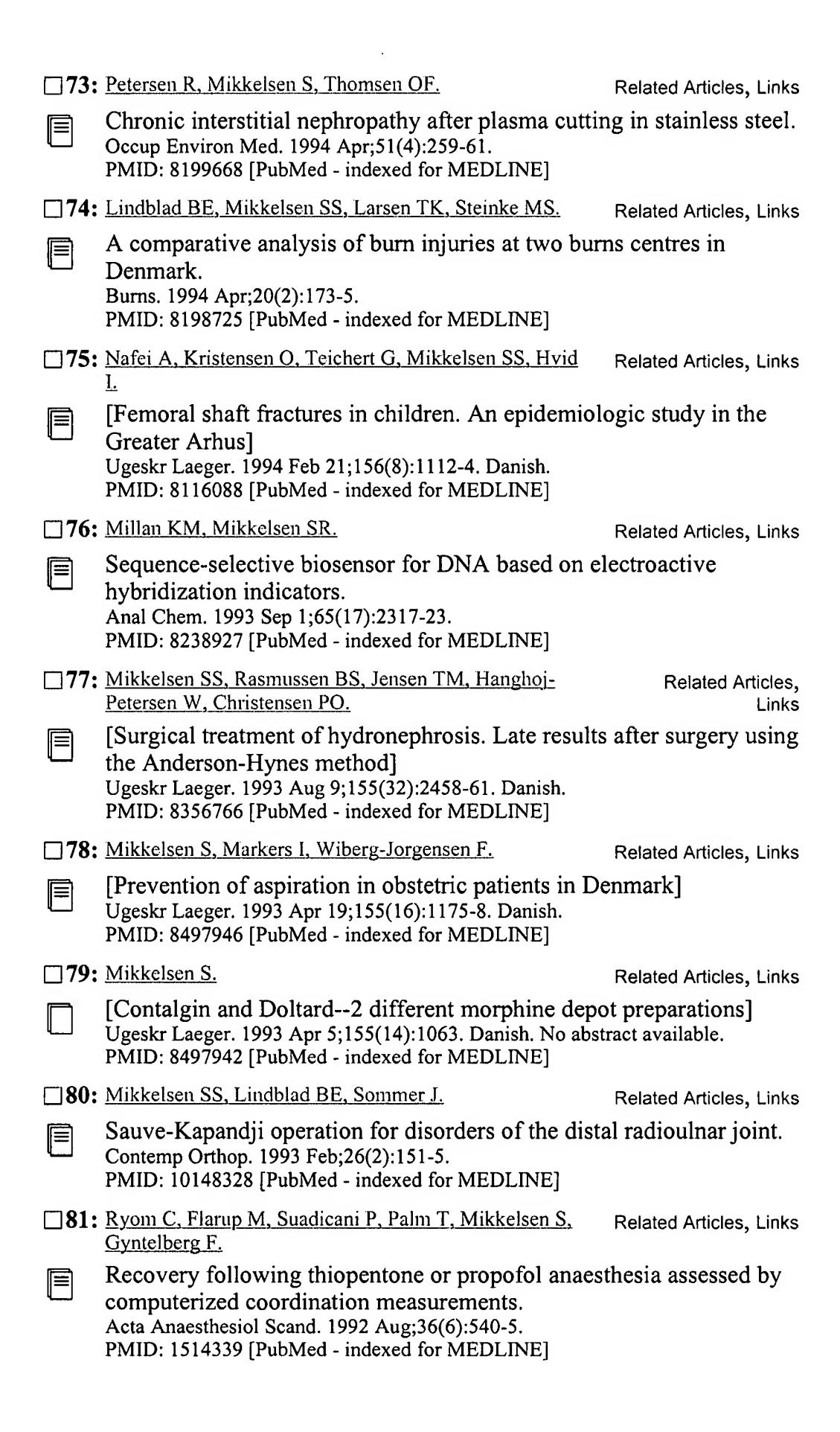
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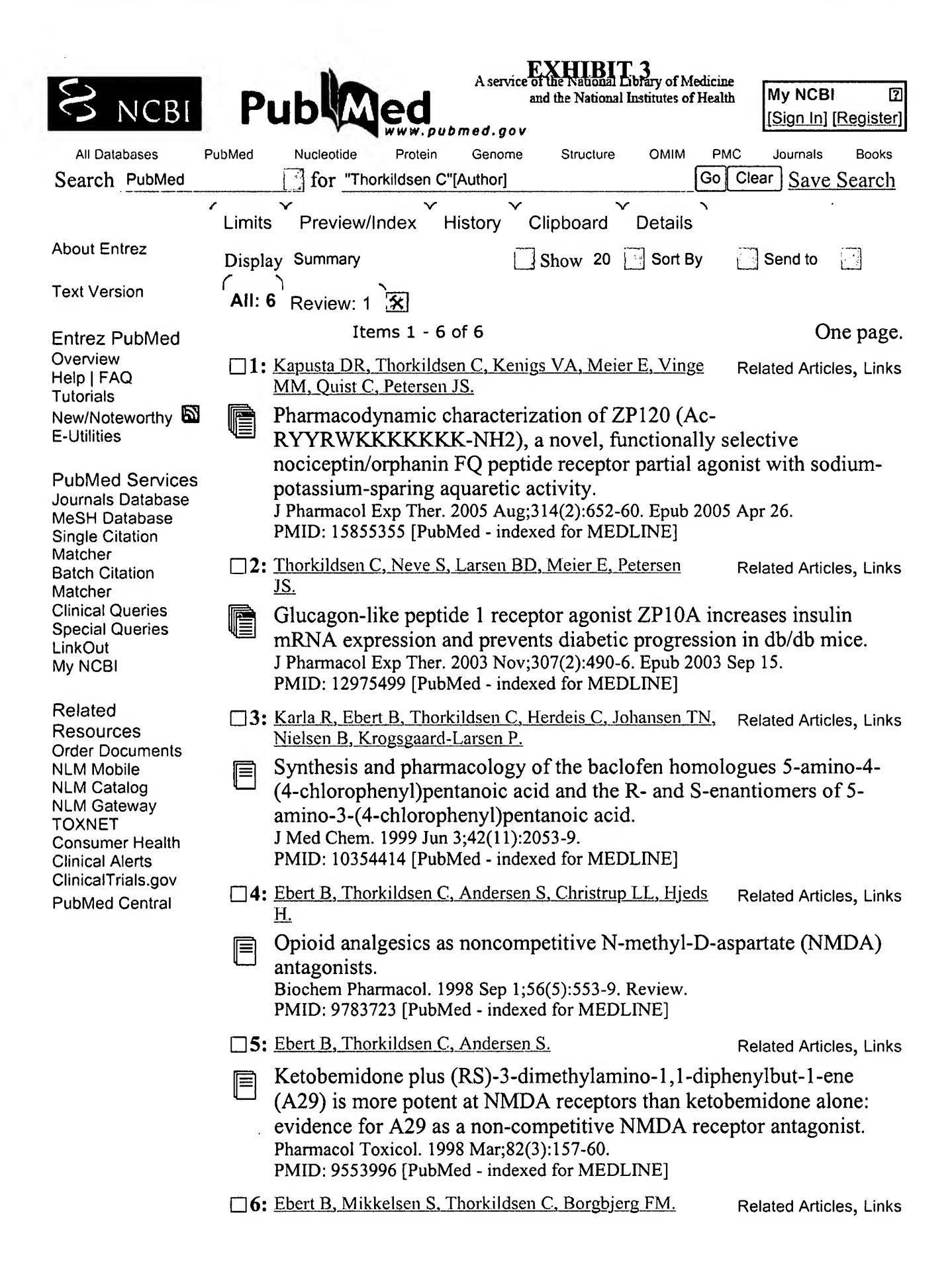
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Norketamine, the main metabolite of ketamine, is a non-competitive NMDA receptor antagonist in the rat cortex and spinal cord.

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